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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/632,422	08/04/2000	Berton Gunter	MERK-0004/20671	1928

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EXAMINER
ZEMAN, MARY K

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 01/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

	Application No.	Applicant(s)
Offic Action Summary	09/632,422	GUNTER, BERTON
	Examiner	Art Unit
	Mary K Zeman	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _04 November 2002_ .

2a)☐ This action is **FINAL.**   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1-58_ is/are pending in the application.

    4a) Of the above claim(s) _10-58_ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _1-9_ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _04 August 2000_ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

    If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

        1.☐ Certified copies of the priority documents have been received.

        2.☐ Certified copies of the priority documents have been received in Application No. _____ .

        3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

    a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _4_ .

4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election of Group I, claims 1-9 in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 10-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

Information Disclosure Statement

The IDS filed 4/9/01 has been entered and considered. An initialed copy of the form PTO-1449 is included with this action.

Drawings

The two sheets of drawings with three figures filed with the application are acceptable to the Examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over TIGR Microarray Data Analysis System (MIDAS) 1999.

The claims are drawn to methods of correcting data such as that derived from microarrays for plate, column and row effects. Claims 2-5 and 7-9 merely describe the data, or set forth types of data to be worked upon by the unstated algorithms.

The MIDAS Program by TIGR, discloses the same methods as those being claimed. MIDAS takes raw data from a variety of microarray type experiments, that have plate, column

and row aspects. These raw data are acted upon to determine if there are any systematic row, column or plate effects, then corrects the data according to the results of those analyses.

The difference between the prior art and the claimed invention of claims 2-5, and 7-9 is the recited data sources. These data sources are descriptive information stored on or employed by a machine. This information is fed into a known algorithm whose purpose is to compare or modify those data using a series of processing steps that do not impose a change on the processing steps and are thus nonfunctional descriptive material. Nonfunctional descriptive material cannot render non-obvious an invention that would have otherwise been obvious. See In re Gulack, 703 F.2d 1381, 1385 (Fed. Cir. 1983) and MPEP 2106.

Claims 1-9 are rejected under 103(a) as being unpatentable over the specification indicating all the algorithmic functions are known and used in the art under the name of S-PLUS by MATHSOFT.

As set forth throughout the specification, the MATHSOFT program S-PLUS allows for the analysis of raw data and offers the ability to transform that raw data according to the end use of the data. At page 12 of the specification, the following is set forth: "Commercially available statistical software may be employed to implement many of the functions of the algorithm of the present invention. Such software may for example include S-PLUS statistical data analysis software, produced and/or marketed by MATHSOFT, Inc. of Cambridge, Massachusetts... Examples of S-PLUS code written for the S-PLUS software and employed to implement the positionally correcting algorithm are set forth in the attached appendix." This indicates that it is the commercially available and acknowledged prior art of the S-PLUS software that use used in the invention. The rejected claims do not require any new, novel or unobvious steps not set forth in the S-PLUS software. The specification and appendix merely choose various functions from known and commercially available software, and align them to perform a certain task. For example, at pages 14, lines 9-10, page 15, lines 4-5, and 25-27, page 16, lines 27-29, page17, lines 10-17, and page 18 lines 10-13, lines 17-30, (among others) the specification repeatedly points out that various features are either well known in the art, or provided by the S-PLUS software.

The difference between the prior art and the claimed invention of claims 2-5, and 7-9 is the recited data sources. These data sources are descriptive information stored on or employed by a machine. This information is fed into a known algorithm whose purpose is to compare or modify those data using a series of processing steps that do not impose a change on the processing steps and are thus nonfunctional descriptive material. The claimed invention uses known software to solve a known problem in a conventional manner. See pages 12-30 of the specification acknowledging known prior art computer assisted data analysis and modification techniques used in the methods set forth therein. Neither the specification, nor the claims set forth any special, non-obvious modifications to the known, conventional software and method steps. A method of using a known program (e.g. S-PLUS known in the prior art to MATHSOFT) for its known purpose to compare and modify data sets does not become non-obvious merely because new data becomes available for analysis. Nonfunctional descriptive material cannot render non-obvious an invention that would have otherwise been obvious. See In re Gulack, 703 F.2d 1381, 1385 (Fed. Cir. 1983) and MPEP 2106.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over SCANALYZE (1998) by Eisen.

The SCANALYZE Program by Stanford University and Michael Eisen, discloses the same methods as those being claimed. SCANALYZE takes raw data from a variety of microarray type experiments, that have plate, column and row aspects. These raw data are acted upon to determine if there are any systematic row, column or plate effects, then corrects the data according to the results of those analyses.

The difference between the prior art and the claimed invention of claims 2-5, and 7-9 is the recited data sources. These data sources are descriptive information stored on or employed by a machine. This information is fed into a known algorithm whose purpose is to compare or modify those data using a series of processing steps that do not impose a change on the processing steps and are thus nonfunctional descriptive material. Nonfunctional descriptive material cannot render non-obvious an invention that would have otherwise been obvious. See In re Gulack, 703 F.2d 1381, 1385 (Fed. Cir. 1983) and MPEP 2106.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. ArrayVision and ArrayStat Software packages, with trademark dates of 1999. The user manuals are unavailable to the Examiner at the time of this Action. Promotional materials are provided. These software assert they provide "Normalization methods for removal of systematic error associated with arrays."

GeneMaths (January 2000) program from Applied Maths. This is a package for the "complete analysis of high density microarrays amd gene chips."

Biosieve program Expression Sieve promotional materials (2002) This program is for microarray data analysis.

Strehlow, D. Software for Quantitation and Visualization of Array Data (Biotechniques 29: 118-121 (July 2000).

Glassey (USP 5,604,854), Rabenhorst (USP 6,384,847) and Malloy (USP 6,205,447) are representative of programs for multidimensional database management.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

Official fax numbers for this Art Unit are: (703) 308-4242, (703) 872-9306. An *unofficial* fax number, direct to the Examiner is (703) 746 5279. Please call prior to use of this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC1600 Receptionist whose telephone number is (703) 308-0196.

mkz
1/22/03

MARY K. ZEMAN
PRIMARY EXAMINER